UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

IN RE GPC BIOTECH AG SECURITIES LITIGATION	**ECF Case** **07-CV-06728 (DC)**

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

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Lead Plaintiff, Axxion S.A. Luxemburg ("Plaintiff" or "Axxion") respectfully submits this Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Consolidated Class Action Complaint (the "Complaint").

PRELIMINARY STATEMENT

Defendant, GPC Biotech AG ("GPC" or the "Company") owns the rights to the experimental anti-cancer drug, satraplatin. During the class period, December 5, 2005 through July 24, 2007, the Company sought fast track designation and accelerated approval from the United States Food and Drug Administration ("FDA") to market the drug in the United States. To comply with the accelerated approval process, GPC was required to conduct a clinical trial to demonstrate the drug's effectiveness in treating prostate cancer. Defendants claimed that the clinical trial showed that satraplatin was effective, not at prolonging the lives of patients taking the drug, but in forestalling further progression of this form of cancer. Defendants called this measure of success "progression-free survival" or "PFS," which they said served as a surrogate for overall survival.

Defendants led investors to believe that a showing of enhanced, progression-free survival would lead to accelerated approval of the drug. To demonstrate their point, Defendants made specific, affirmative, unequivocal statements, prior to and during the class period, that the FDA had approved PFS as a benchmark, or "endpoint" for the clinical trial and that a showing of improved overall survival would not be required. In the GPC Annual Report for 2006, Defendants wrote:

> "**Based upon an *agreement* reached with the FDA in 2005**, the primary endpoint of the Phase 3 registrational trial for accelerated approval by the FDA will be progression-free survival."

The GPC Annual Report for 2005 similarly stated:

> "As *agreed* with the FDA…, the primary endpoint for the SPARC trial is progression-free survival and the secondary endpoints are overall survival and time to pain progression."

On July 24, 2007, the FDA's true position on this important issue was publicly revealed for the first time. On that date, the FDA issued a "Briefing Document" relating to GPC's application for accelerated approval of satraplatin, announcing that it was deferring a ruling on GPC's application. In that document, the FDA's Oncology Drugs Advisory Committee revealed that it "clearly communicated to the Applicant during the development phase" that it had "no experience with this [progression-free survival] endpoint." Thus, contrary to what Defendants represented in GPC's public filings, it became clear on that date that Defendants never had an "agreement" with the FDA in 2005 or any time thereafter to use progression-free survival as an endpoint for GPC's clinical trial.

GPC's stock price tumbled on the news, losing over 50% of its value. Analysts following the Company remarked that the FDA committee's report came as a shock because what the FDA committee stated in its report was entirely inconsistent with what Defendants had been saying in the months leading up to the FDA committee hearing.

Axxion alleges in its Complaint that Defendants made materially false and misleading statements by claiming that GPC had reached an agreement with the FDA to use PFS as the primary endpoint for its clinical trial. In their motion to dismiss the Complaint, Defendants claim that the FDA did not mean what it said. Defendants contend that Plaintiff misunderstood the meaning of the FDA Briefing Document. Defendants argue that what the FDA really meant was that it had no prior experience with the tests GPC used to demonstrate that satraplatin was effective in achieving the "composite" PFS endpoint. As such, Defendants argue, Plaintiff is wrong to claim that the FDA told GPC early on that the endpoint itself was unacceptable.

Plaintiff believes that its understanding of the FDA's unambiguous statement is the correct one. The FDA could easily have chosen more precise language to convey the message as Defendants interpret it. However, even if Defendants' spin is correct, Defendants' statements during the class period were still false and misleading. The FDA "clearly communicated" something to GPC "during the development phase" of the clinical trial. That something was either 1) that the FDA had no experience with the use of PFS as a primary endpoint, as Plaintiff claims the FDA committee's Briefing Document states, or 2) that the FDA was unfamiliar with the composite elements Defendants utilized to demonstrate progression-free survival. Either way, it was misleading for Defendants to claim that they had an "agreement" with the FDA on this issue. Assuming for the sake of argument that Defendants' interpretation is correct, it was still misleading to state that there was an agreement that GPC could use the PFS endpoint in its application without also disclosing the FDA's concerns, and lack of experience, with the manner in which GPC intended to demonstrate it.

As set forth below, Plaintiff's Complaint specifically identifies false and misleading statements made by two of the Company's officers and in the name of the Company itself. It shows how these false and misleading statements and omissions caused GPC's price to be artificially inflated, and it shows how GPC's stock price fell when the truth was revealed in the FDA Briefing Document. It further details Defendants' motive and opportunity to commit fraud, and alleges in detail how Defendants' statements were made with the requisite scienter. The Complaint further contains well-pled allegations showing that all of the individuals named as Defendants traded on inside information, and how each of them was a "control person" of the Company. Plaintiffs' Complaint satisfies all of the pleading requirements for a claim brought

under Sections 10(b), 20(a) and 20(A) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t(a), and 78t-1(a). Accordingly, Defendants' motion to dismiss should be denied.

STATEMENT OF FACTS

GPC Biotech AG ("GPC) was founded in 1997 by Individual Defendants Mirko Scherer ("Scherer"), Elmar Maier ("Maier) and Sebastian Meier-Ewert (Ewert).[1] In 2002, GPC licensed the exclusive commercial rights to satraplatin, and its development became the Company's primary focal point.[2] Along with the commercial rights came two U.S. patents, the first of which expired in 2008. These patents in effect gave GPC the exclusive right to pursue FDA approval of satraplatin until patent protection expired.[3]

GPC was not permitted to sell satraplatin in the United States until it obtained approval from the FDA. Obtaining this approval is a lengthy process, involving preclinical testing, submission of an investigational new drug application, clinical trials, and a final approval application and hearing. Where, like here, there is no other drug available in the marketplace that effectively treats the disease in question, the FDA offers what is known as "fast track" designation to expedite the drug review process.[4]

Defendants pursued fast track designation from the outset, with a goal of obtaining accelerated approval in 2007, before the first of two patents expired.[5] In July, 2003, representatives of GPC met with the FDA in an official "End-of-Phase 2" meeting. Following

[1] *See* Plaintiffs' Consolidated Class Action Complaint ¶¶ 30, 33, 34 and 35 ("Comp. ¶__). Unless otherwise indicated, references to "Individual Defendants" include Scherer, Maier, Ewert and Bernd R. Seizinger ("Seizinger") and references to "Defendants" includes the four Individual Defendants and GPC.

[2] Comp. ¶¶ 46, 48.

[3] Comp. ¶ 49.

[4] Comp. ¶¶ 50, 51.

[5] Comp. ¶¶ 49, 52.

this meeting, GPC was permitted to commence clinical testing of satraplatin. Enrollment in the clinical trial began in September, 2003.[6]

Following the End-of-Phase 2 meeting, detailed discussions regarding the parameters of the clinical study were discussed. During those discussions, Defendants sought acceptance of an "endpoint" which would measure the trial's success by a slowdown in prostate cancer progression rather than the more traditional overall survival test.[7]

On June 9, 2004, GPC filed a Registration Statement with the SEC, offering 7.4 million shares of GPC in the form of American Depository Shares. In amended registration statements filed on June 10, 2004 and July 1, 2004, Defendants stated:

> We have elected to seek approval under the accelerated approval process for satraplatin. Under the terms of the Special Protocol Assessment, the primary endpoint of the Phase 3 registrational trial will be the time to disease progression. [emphasis added].

"Time to disease progression" is another term for progression-free survival (PFS). Each of the Individual Defendants signed these registration statements.[8] This declaration regarding the trial's "primary endpoint" was never withdrawn.

On at least two other occasions, the Company stated in SEC filings that the FDA had approved PFS as the measure of success for the clinical trials. On June 21, 2007, GPC filed its annual report on Form 20-F. Defendants Seizinger and Scherer signed the report. In the SEC filing, the Company wrote:

> **Based upon an agreement reached with the FDA in 2005,** the primary endpoint for the Phase 3 registrational trial for accelerated approval by the FDA will be progression-free survival**.** (emphasis added).

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[6] Comp. ¶¶ 53, 54, 58.

[7] Comp. ¶¶ 54-57.

[8] Comp. ¶¶ 60-61.

Fourteen months earlier, on April 3, 2006, GPC filed its annual report for 2005. In this report, GPC stated:

> "**As agreed with the FDA**…, the primary endpoint for the SPARC trial is progression-free survival and the secondary endpoints are overall survival and time to pain progression." (emphasis added)[9]

Preliminary reports issued by Defendants indicated that the Phase 3, "SPARC" trials were going well. On September 24, 2006, and on November 9, 2006, GPC issued press releases claiming that satraplatin was proving effective when measured for PFS.[10] Not surprisingly, stock analysts including Needham & Company, Piper Jaffray, and West LB, began touting GPC as an investment.[11]

The Company purported to present "strong", "detailed" "final progression-free survival (PFS) results" at the ASCO Prostate Cancer Symposium in Orlando in February, 2007. One of many analysts attending this symposium came away from it projecting that satraplatin had the potential to be a $1 billion drug. Trial results were also touted in a press release issued by the Company on April 1, 2007 and again on May 15, 2007.[12]

On May 15, 2007, the Company announced that the FDA would consider the Company's application for satraplatin at a hearing on July 24, 2007.[13]

On June 4, 2007, GPC presented data at an oncology conference in Chicago, again touting the results of the clinical trial and its support for the claim that satraplatin achieved progression-free survival benchmarks.[14]

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[9] Comp. ¶¶ 72, 73, 95.
[10] Comp. ¶¶ 77, 78.
[11] Comp. ¶¶ 82-84.
[12] Comp. ¶¶ 86-91.
[13] Comp. ¶ 92.
[14] Comp. ¶ 94

On June 21, 2007, the Company filed its annual report with the SEC, reminding investors that the FDA had approved PFS as a primary endpoint and that results of the SPARC clinical trial showed the drug's effectiveness when measured in that manner.[15] The stage was set.

GPC's stock price reflected the bullishness expressed by the Defendants. In December, 2005, GPC's shares traded in Europe at €10.86 per share. By May, 2007, the price per share had doubled. The Individual Defendants took advantage of the rising stock price by selling a significant number of their shares. All told, the Individual Defendants sold more than 15 million shares of GPC common stock for gross proceeds of approximately $39 million during the class period.[16]

On July 20, 2007, Defendants' scheme unraveled. On this date, Defendants were informed by the FDA that at the hearing a few days later, it would question Defendants on, among other matters, the PFS endpoint used by the Company in its application. The FDA committee reminded Defendants that it had "clearly communicated" to them during the development phase of the process that it was unfamiliar with the PFS endpoint. With this news, the Company's shares lost one-third of their value.[17]

These preliminary concerns were confirmed at the formal meeting on July 24, 2007. By a 12-0 vote, the panel voted to delay its ruling on GPC's application for fast track approval. The first of five reasons provided by the FDA committee considering the application was that the "FDA has no prior experience with this endpoint. This was clearly communicated to the Applicant during the development phase."[18]

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[15] Comp. ¶ 95.

[16] Comp. ¶¶ 16, 32-35, 65, 79, 99.

[17] Comp. ¶ 101.

[18] Comp. ¶ 104.

Securities analysts, who had been led to believe that the Company and the FDA had reached an agreement on use of the PFS endpoint, were shocked. "It appears the clinical trial design and endpoints for the SPARC study were never signed off on by the agency…" wrote an analyst for Friedman Billings. As reported on Forbes.com, "the FDA insisted, fairly strenuously, that it had let the biotech know that its measures of disease progression and pain were not valid." Additional criticism was leveled by analysts for Deutsche Bank, Societe Generale, and Credit Suisse.[19]

On December 4, 2007, Defendant Scherer resigned his position with the Company. Defendants Maier and Ewert announced their departures on February 25, 2007. GPC also announced that final results of the overall survival testing failed to show a statistically significant benefit to those participating in the clinical trial.[20]

ARGUMENT

I. Standard of Review

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the factual allegations of a complaint. In this Circuit, courts must "'accept as true all of the factual allegations contained in the complaint' and 'draw all inferences in the light most favorable to the [plaintiff].'" *In re Scottish Re Group Sec. Litig.*, 524 F. Supp. 2d 370, 382 (S.D.N.Y. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1964 (2007)).

In testing the legal sufficiency of the Complaint, the standard to be applied is one of plausibility. *Twombly* stands for the principle that the Court should apply a flexible plausibility analysis "which obliges a pleader to amplify a claim with some factual allegations in those

[19] Comp. ¶¶ 106-110.

[20] Comp. ¶¶ 114-116.

contexts where such amplification is needed to render the claim plausible." *Iqbal v. Hasty,* 490 F.3d 143, 157-58 (2d Cir. 2007).

When considering a motion to dismiss, "the court is not limited to the face of the complaint. The court 'may also consider any written instrument attached to the complaint, statements or documents incorporated into the complaint be reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff upon which it relied in bringing the suit.'" *Scottish Re Group*, 524 F. Supp. 2d at 382 (quoting *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.,* 493 F.3d 87, 98 (2d Cir. 2007)).

II. The Complaint States A Claim for Violations of Section 10(b)

To state a claim under Section 10(b) and Rule 10b-5, 17 C.F.R. § 240.10b-5, plaintiff must allege that defendants, in connection with a purchase or sale of securities, with scienter, made a material false representation or omitted to disclose material information, upon which plaintiff relied, proximately causing plaintiff to suffer injury. *Lentell v. Merrill Lynch & Co.,* 396 F.3d 161, 172 (2d Cir. 2005).

The Complaint satisfies these pleading requirements.

A. The Complaint Identifies Misrepresentations and Omissions of Material Fact with the Requisite Specificity

Plaintiff's Complaint centers upon Defendants' statements that an agreement with the FDA was in place to allow GPC to use PFS as a primary endpoint in connection with its application for accelerated approval of satraplatin.[21] Defendants admit that these statements

[21] Comp. ¶ 95 (In GPC's 2006 annual report, Defendants wrote: Based upon an agreement reached with the FDA in 2005, the primary endpoint of the Phase 3 registrational trial for accelerated approval by the FDA will be progression-free survival"). *See also* Comp. ¶¶ 60, 72.

were made in GPC's annual reports, and that these statements were identified by Plaintiffs as false and misleading.[22]

Plaintiff contends the FDA never consented to GPC's use of PFS as a primary endpoint for the clinical trials. On July 20, 2007 and again on July 24, 2007, the FDA committee reviewing GPC's application for approval of satraplatin wrote: "The FDA has no prior experience with this endpoint. This was clearly communicated to the Applicant during the development phase."[23]

The Complaint also identifies numerous other statements which, by omission, are misleading.[24] Having conditioned the market to believe that it was on track to obtain fast track approval from the FDA, it was clearly misleading for Defendants to report that the clinical trials were showing strong progression-free survival results without disclosing that the FDA had not agreed to the use of PFS as an endpoint.[25]

In the instance of each misrepresentation and omission, the Complaint identifies the specific statement Plaintiff contends is fraudulent, the person(s) responsible for or who made that statement, where and when the statement was made, and why the statement was fraudulent. This is all that is required. *Scottish Re Group*, 524 F. Supp. 2d at 383.

Defendants contend that the Complaint fails to identify a single misrepresentation or omission. In support, they first argue that Plaintiff's premise is incorrect, and that the FDA

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[22] *See* Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint ("Defendants' Brief") at p. 10, fn. 9 ("Plaintiffs only identify two affirmative statements in GPC's 2005 20-F and 2006 20-F as potentially false, and these are statements that the FDA had agreed that PFS would be the primary endpoint for accelerated approval. Comp. ¶¶ 72, 95").

[23] Comp. ¶¶ 101, 104. References, *infra*, to the "FDA Briefing Document" are to the July 24, 2007 FDA Briefing Document, attached as Ex. 8 to the Affidavit of Bernard J. Garbutt III.

[24] *See, e.g.,* Comp. ¶ 62, where Defendants tout the achievement of target enrollment in the clinical trial and the importance of this accomplishment in allowing GPC to move forward in getting FDA approval, without mentioning the concerns raised by the FDA with regard to the PFS endpoint of the study.

[25] *See* Comp. ¶¶ 78, 86, 89, 94.

committee deferred ruling on GPC's application to market satraplatin for reasons that had nothing to do its lack of familiarity with the PFS endpoint. Second, Defendants argue that to the extent a misrepresentation or omission is alleged, it is not pled with sufficient particularity. Finally, in a footnote, Defendants state that they warned investors that FDA approval may not come to pass and, as such, they should not be held accountable when it did not.[26] Defendants are incorrect on all counts.

1. The Inferences Defendants Draw From the July 24, 2007 FDA Committee Report are Inconsequential to Plaintiff's Claim

The FDA committee's Briefing Document cited five reasons for the decision to defer ruling on GPC's application for accelerated approval to market satraplatin. The first reason concerned GPC's use of PFS as a primary endpoint. With regard to this use, the FDA Committee stated:

> The FDA has no prior experience with this endpoint. This was clearly communicated to the Applicant during the development phase. FDA will seek ODAC advice on the acceptability of this composite endpoint as the basis of marketing approval.[27]

Defendants argue that the proper inference to be taken from this statement is not, as Plaintiff claims, that the FDA did not consent during the development phase of the clinical trial to the use of the PFS endpoint, but rather, that the FDA took issue with the "particular definition" of PFS used in GPC's clinical trial. Moreover, Defendants claim, GPC's use of the PFS endpoint played no role in the FDA committee's decision to defer its ruling on GPC's application.[28]

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[26] Defendants' Brief at 16-17, fn. 18.

[27] *See* Ex. 8 to Affidavit of Bernard J. Garbutt III, p. 3.

[28] Defendants' Brief at 13-17.

The report states however that the FDA committee "has no prior experience with *this endpoint*."[29] This is entirely inconsistent with the notion that the FDA approved GPC's use of PFS as a primary endpoint for the clinical trial but did not agree with the definition. The FDA committee could easily have said that the FDA was unfamiliar with the "particular definition" of PFS used by the Company, but that is not what it chose to say.

Plaintiff's interpretation that the FDA did not approve GPC's use the PFS endpoint for the clinical trials is shared by an analyst for Friedman Billings and Ramsey, who reported "GPC had been handling the discussions with the FDA, and it appears the clinical trial design *and endpoints* for the SPARC study were never signed off on by the agency even though both investors and Spectrum were under the impression they had been."[30]

In moving to dismiss the Complaint, Defendants provide a different interpretation of "this endpoint." In the context of this case, however, Defendants' spin is not particularly meaningful. Assuming Defendants' interpretation is the correct one, and the FDA committee's lack of experience was not with the PFS endpoint generally but rather with the tests employed and the manner in which Defendants attempted to demonstrate the progression-free success of satraplatin, then it was concerns about the testing methodology that the FDA "clearly communicated" to Defendants.

Neither the annual reports, nor any other statements made by Defendants, qualified Defendants' assertion that the FDA *had agreed* to GPC's use of PFS as a primary endpoint for the clinical trials. Defendants never stated that while the FDA approved the use of PFS as a primary endpoint in the abstract, it had not agreed, and was not familiar with, the manner in which GPC would attempt to demonstrate progression-free survival. In reporting positive results

[29] Comp. ¶ 104.

[30] Comp. ¶ 106.

from the clinical trials, Defendants never stated that FDA approval was still at risk because the agency, which had already approved the PFS endpoint, raised specific concerns with the elements of that endpoint or the Company's methodology for demonstrating it.

Under either interpretation of the FDA Briefing Document, the statements identified in the Complaint are in fact misleading. At best, Defendants' argument creates issues to be determined by a fact finder, not on a motion to dismiss.

2. The Complaint's Key Allegation is Pled with the Requisite Specificity

A complaint alleging securities fraud must satisfy Rule 9(b)'s requirement that "the circumstances constituting fraud…be stated with particularity." *Scottish Re Group*, 524 F. Supp. 2d at 383. A plaintiff satisfies Rule 9(b) by "(1) specify[ing] the statements that the plaintiff contends were fraudulent, (2) identify[ing] the speaker, (3) stat[ing] where and when the statements were made, and (4) explain[ing] why the statements were fraudulent." *Id.* (quoting *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004)).

"Rule 9(b) must still be read in light of the liberal pleading requirement of Rule 8, which only requires a 'short and plain statement' of the claim. Plaintiffs are not required to plead detailed evidence." *Glidepath Holdings B.V. v. Spherion Corp.*, No. 04-9758, 2007 U.S. Dist. LEXIS 54889, at *30 (S.D.N.Y. July 26, 2007) (internal quotations omitted). Therefore, "allegations may be made on information and belief where the fraud is based on matters within the adverse party's sole knowledge," if they are accompanied by a statement of the facts upon which the belief is founded." *Id.*

The Complaint easily satisfies these standards and Defendants cite no examples where this standard is not met. Plaintiff's allegations identifying the 2006 annual report as false and misleading provide a good example. In paragraphs 95 and 96 of the Complaint, Plaintiffs state their allegation that the 2006 annual report was misleading in stating that the FDA agreed to the

use of PFS as a primary endpoint for the clinical trials. Plaintiffs identify the statement they claim is fraudulent, in bold. The Complaint identifies the Company as the entity that filed the report, and Seizinger and Scherer as signators. The Complaint correctly identifies the date of filing, and the fact that the document was filed with the SEC. Most importantly, it explains in paragraph 96 the basis for Plaintiff's claim that the statement was misleading.

Defendants cite *Garber*[31] for the proposition that the burden is on Plaintiff to allege "the who, what, when, where and how of the alleged fraud."[32] As set forth in the example above, Plaintiff satisfies this pleading standard. The standard was not satisfied in *Garber* because there was no document like the FDA Briefing Document in this case that could be cited as providing a basis for plaintiff's claim that the statements in question were false and misleading.

3. The So-Called "Warnings" of Non-Approval Were Inadequate

In a footnote, Defendants, again citing *Garber,* argue that where circumstances causing the plaintiff's losses were the subject of explicit risk factors identified by defendants, liability will not attach.[33] Defendants claim that GPC investors were warned that the FDA committee might not approve its application for fast track approval, and as such, they were aware that what came to pass just might.

Defendants' argument misses the point. The misrepresentation is that Defendants failed to disclose what the FDA said – not that they failed to advise that GPC might not obtain accelerated approval for satraplatin.

The difference between *Garber* and the case at bar is significant. In *Garber*, investors claimed that the Prospectus was misleading in its failure to disclose an increase in broker

[31] *Garber v. Legg Mason, Inc.,* 537 F. Supp. 2d 597, 614 (S.D.N.Y. 2008) (quoting *U.S. ex rel. Woods v. Empire Blue Cross & Blue Shield*, No. 99-4968, 2002 U.S. Dist. LEXIS 15251, at *4 (S.D.N.Y. Aug. 19, 2002)).

[32] Defendants' Brief at 10.

[33] Defendants' Brief at 16-17.

attrition and customer withdrawals. Plaintiffs provided no facts or evidence to support the allegation. In addition, the Prospectus disclosed the specific risk of customer withdrawals and the loss of key investment personnel, risks that had not yet come to fruition. *Garber,* 537 F. Supp. 2d at 613. In the case at bar, Plaintiff provides proof in the form of the FDA Briefing Document that Defendants were told by the FDA that it was unfamiliar with the PFS endpoint (or the elements of this endpoint as Defendants claim) long before the annual report were filed. This was never disclosed to investors. To the extent Defendants provided investors with any warnings, such warnings related only to the general risks that its satraplatin application might not be approved by the FDA. "[A]ll the cautionary language in the world will not replace a true material omission or misstatement of fact which would matter to a reasonable investor." *In re Integrated Res. Real Estate Ltd., P'ships Sec. Litig.,* 815 F. Supp. 620, 674 (S.D.N.Y. 1993).

4. Seizinger and Scherer Are Responsible for Statements They Made and for Statements Made in the Name of the Company

Defendants seek to absolve defendants Seizinger and Scherer of any Section 10(b) liability for the misstatements (and omissions) in SEC filings and press releases that are not specifically attributed to them. In doing so, they urge this Court to ignore clear precedent in this Circuit permitting what is known as "group pleading," which allows plaintiffs to rely on "a presumption that statements in prospectuses, registration statements, annual reports, press releases, or other group-published information, are the collective work of those individuals with direct involvement in the everyday business of the company." *Shanahan v. Vallat*, No. 03-3496, 2004 U.S. Dist. LEXIS 25523, at *11-12 (S.D.N.Y. Dec. 19, 2004) (quoting *In re Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133, 142 (S.D.N.Y. 1999)). Plaintiff can invoke the group pleading doctrine by alleging "that the defendant was a corporate insider or affiliate with direct

involvement in the daily affairs of the company." *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 440-41 (S.D.N.Y. 2005).

As specifically alleged in the Complaint, Defendant Seizinger has served as the Chief Executive Officer ("CEO") of GPC since 1998. Defendant Scherer was, until, December 4, 2007, the Company's Chief Financial Officer ("CFO") as well as one of the Company's co-founders. Given their prominent positions within the Company, they qualify as insiders with "direct involvement in the everyday business of the company." *Shanahan,* 2004 U.S. Dist. LEXIS 25523, at *11-12.

While courts sometimes impose more strict pleading requirements on plaintiffs alleging securities fraud, restricting "group pleading" allegations is not one of them. Defendants specifically acknowledge that "group pleading" is allowed in the Second Circuit.[34] Defendants are correct. *See In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 642 (S.D.N.Y. 2007) ("this Court joins the majority of district courts in this district and others in holding that the group pleading doctrine is 'alive and well.'"); *In re Marsh & McLennan Cos. Sec. Litig.*, 501 F. Supp. 2d 452, 479 (S.D.N.Y. 2006) ("Defendants' argument that group pleading is no longer permissible under the PSLRA is rejected.").[35] Accordingly, defendants Seizinger and Scherer

[34] Defendants state that they are "aware that courts within this district have held that the group pleading doctrine survived the passage of the PSLRA." Defendants' Brief at 18, fn. 20.

[35] *See also In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 449 (S.D.N.Y. 2005)("the group pleading doctrine has survived the passage of the PSLRA"); *BISYS*, 397 F. Supp. 2d at 439 (court applied group pleading doctrine post-PSLRA); *In re Bayer AG Sec. Litig.*, No. 03-1546, 2004 U.S. Dist. LEXIS 19593, (S.D.N.Y. Sept. 30, 2004) (relying on group pleading doctrine in post PSLRA case); *In re Complete Mgmt. Inc. Sec. Litig.,* 153 F. Supp. 2d 314, 326 n.7 (S.D.N.Y. 2001) ("Nothing in the PSLRA has changed the group pleading doctrine…."); *In re Solv-Ex Corp. Sec. Litig.*, 210 F. Supp. 2d 276, 283 (S.D.N.Y. 2000) ("The PSLRA has not abolished the use of group pleading in Section 10(b) cases.")

are responsible for their own statements and the Company-issued statements under the group pleading doctrine.[36, 37]

B. The Complaint Alleges a Causal Connection Between the Misrepresentations and Omissions and the Losses Plaintiff Sustained

Plaintiff alleges that GPC's stock artificially rose to "well over $30 per share" as a result of misleading statements and omissions made by Defendants with regard to the purported success of satraplatin in the Company's clinical trials and "the FDA's comments about acceptable endpoints."[38] When the truth became known that the FDA had not agreed to the use of PFS as the primary endpoint for the clinical trial (or as Defendants contend, when the truth became known about the FDA's lack of familiarity with the tests used by GPC to demonstrate PFS success), GPC's stock price plummeted over 50%.[39] On the two trading days after the FDA committee's true view of GPC's use of PFS as a primary endpoint became known, July 20, 2007, the Company's stock dropped $10.85.[40] Plaintiff has clearly alleged not only that GPC's stock price was inflated by misleading statements about FDA approval of GPC's use of the PFS endpoint; Plaintiff has also alleged that disclosure of the truth regarding the FDA's position with respect to the endpoint led to the stock price's decline.

At the pleading stage, the complaint must "provide a defendant with some indication of …the causal connection that plaintiff has in mind." *Dura Pharms., Inc. v. Broudo,* 544 U.S. 336, 337 (2005). A plaintiff has properly pleaded loss causation by alleging "that the subject of the

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[36] To the extent Defendants contend that Plaintiff seeks to apply the group pleading doctrine to defendants Ewert and Meier, they are not correct. Plaintiffs name Scherer and Seizinger, but not Ewert or Meier, in its §10(b) count. *See* Comp. ¶ 36.

[37] Defendants correctly point out that the Complaint inadvertently did not include the Company itself under the §10(b) Count. Plaintiff intended to do so, and its omission is an oversight.

[38] Comp. ¶¶ 119, 120.

[39] Comp. ¶ 122

[40] Comp. ¶ 101.

fraudulent statement or omission was the cause of the actual loss suffered, *i.e.* that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Lentell,* 396 F.3d at 173 (quoting *Suez Equity Investors, L.P. v. Toronto-Dominion Bank*, 250 F. 3d 87, 95 (2d Cir 2001)). This requirement, however, "ought not place unrealistic burdens on the plaintiff at the initial pleading stage." *Caremark v. Coram Healthcare Corp.,* 113 F.3d 645, 649 (7th Cir. 1997). Moreover, there is no burden to allege that the misrepresentation in question is the sole reason for the loss. *Robbins v. Koger Props. Inc.,* 116 F.3d 1441, 1447 n.5 (11th Cir. 1997). Plaintiff more than satisfies this pleading standard.

Plaintiff has clearly provided Defendants with an indication of the causal connection it has in mind. While there may have been reasons for the sharp decline in GPC's stock price in July 2007 in addition to the FDA committee's Briefing Document indicating that the FDA and GPC did not have a meeting of the minds with regard to that endpoint, this paramount issue is alleged to have caused at least some of the fall of GPC's stock price and, as such, loss causation is adequately pled.

Defendants disagree. They claim that GPC's stock price was neither inflated by the statements and omissions regarding the FDA's agreement to allow GPC to use PFS as the primary endpoint, nor deflated when the FDA announced that it was deferring its ruling on GPC's application. To show that the price of GPC's stock was not inflated by the statements in the annual reports that the FDA had approved PFS as an endpoint, Defendants once again ask the court to accept their argument that the FDA's agreement to allow GPC to use the PFS endpoint for its clinical trials was only in concept, and that the FDA did not approve PFS as an endpoint as GPC intended to reach it. As such, Defendants argue, the price was not inflated because the FDA never agreed to the use of the composite endpoint as Defendants intended to demonstrate it.

To show that GPC's stock did not deflate after the FDA announced its concerns and lack of familiarity with the PFS endpoint, Defendants point to the other reasons cited in the FDA Committee report as the real cause for the drop in GPC's stock.[41]

Defendant may disagree with Plaintiff's premise. Defendant may be right that there were other causes in addition to those cited by Plaintiff that led to the rise and fall of GPC's stock price. This is an issue for discovery and the fact finder to determine. But Defendant cannot say that they have not been provided with "some indication of …the causal connection that plaintiff has in mind." No matter how one interprets the FDA committee Briefing Document, it remains the case that the Complaint clearly states the claim that Defendants' misstatements and omissions concealed something from the market which, when disclosed, negatively affected the value of the security. *Lentell,* 396 F.3d at 173. Loss causation is adequately pled.

C. The Complaint's Allegations Give Rise to a Strong Inference of Scienter

A plaintiff states a claim under §10(b) and Rule 10b-5, by alleging facts that provide a strong inference that the defendants acted with scienter, i.e., a mental state embracing intent to deceive, manipulate or defraud. *See Rothman v. Gregor*, 220 F.3d 81, 90 (2d Cir. 2000). A plaintiff satisfies the PSLRA by stating "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."[42]

The Supreme Court recently clarified the "strong inference of scienter" standard in *Tellabs.*[43] The Court held that three "prescriptions" apply when a court is determining the adequacy of scienter allegations: 1) accept all factual allegations in the complaint as true; 2) determine "whether all of the facts alleged, taken collectively, give rise to a strong inference of

[41] Defendants' Brief at 19-22.

[42] 15 U.S.C. § 78u-4(b)(2).

[43] *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007).

scienter"; and 3) after taking into account "plausible opposing inferences" (meaning "nonculpable explanations for the defendants' conduct, as well as inferences favoring the plaintiff") that arise from the Complaint, the complaint will survive if "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." 127 S. Ct. at 2502-03.

The inference of scienter need not, however, be "irrefutable, i.e., of the 'smoking-gun' genre, or even the 'most plausible of competing inferences.'" *Id.* at 2510. If the inferences are equally plausible, the complaint should be sustained. The *Tellabs* court posed the relevant inquiry as being: "[w]hen the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" *Id.* at 2511.

Scienter can be pled either by alleging (a) facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness, or (b) facts to show that defendants had both motive and opportunity to commit fraud. *Novak v. Kasaks*, 216 F.3d 300, 307 (2d Cir. 2000).

1. Plaintiffs Allege Strong Circumstantial Evidence of Defendants' Conscious Misbehavior or Recklessness

Plaintiffs have properly pled facts showing that Defendants acted recklessly or with conscious misbehavior.

Conscious misbehavior requires that the plaintiff allege that defendant's conduct is "at the least, conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Scottish Re Group,* 524 F. Supp. 2d at 385 (citing *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001)). Unlike recklessness,

conscious misbehavior is more easily identified because "it encompasses deliberate illegal behavior . . ." *Novak,* 216 F.3d at 308.

"Recklessness is adequately pled where plaintiffs specifically allege[] defendants' knowledge of facts or access to information contradicting their public statements' or 'where plaintiffs allege[] facts demonstrating that defendants failed to review or check information that they had a duty to monitor, or ignored obvious signs of fraud.'" *In re Winstar Commc'ns*, Nos. 01-CV-3014 (GBD), 01-CV-11522, 2006 U.S. Dist. LEXIS 7618, at *21 (S.D.N.Y. Feb. 24, 2006) (quoting *Novak*, 216 F.3d at 308.) "'An egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of recklessness.'" *Id. (*quoting *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996)).

This Court has stressed that: [s]ecurities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements. Under such circumstances, defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation. *In re Globalstar Sec. Litig.*, No. 01 Civ. 1748 (SHS), 2003 U.S. Dist. LEXIS 22496, at *17 (S.D.N.Y. Dec. 12, 2003) (citing *Novak*, 216 F.3d at 308); *In re Nortel Networks Corp. Sec. Litig*., 238 F. Supp. 2d 613, 631 (S.D.N.Y. 2003).

"One of the classic fact patterns giving rise to a strong inference of scienter is that defendants published statements when they knew facts or had access to information suggesting that their public statements were materially inaccurate." *Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 665 (8th Cir. 2001) (citing *Novak*, 216 F.3d at 311).

In *In re Astrazeneca Securities Litigation,*[44] the Court observed in a recent opinion:

> The key, of course, is the honest belief of the management in the truth of information issued to the public. If the management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public then there is scienter. There is also scienter if the management is reckless in dealing with such adverse facts.

Plaintiffs here have pleaded direct and circumstantial evidence that Defendants knew that prior to filing the Company's 2005 and 2006 annual reports, the FDA had not agreed to GPC's use of PFS as a primary endpoint for the clinical trials (or, as Defendants claim, that the FDA had expressed its lack of experience with the tests Defendants intended to employ to demonstrate the effectiveness of satraplatin from a PFS perspective). There is no escaping this conclusion from any fair reading of the FDA's Briefing Document, which stated that the FDA had **"clearly communicated"** to Defendants during the development phase of the clinical trials that it had "no experience with the PFS endpoint" (or its composite makeup) Defendants sought to employ. Despite this explicit warning that PFS (or its composite makeup) was not familiar to the FDA as a primary endpoint, Defendants recklessly or deliberately ignored the FDA's concerns and lack of experience with the PFS endpoint (or its composite makeup) and stated that such an agreement did, in fact, exist without qualification.[45]

Defendants' decision to misrepresent these material communications with the FDA, and then report positive results based on that misinformation, is powerful direct evidence of scienter. *In re Amylin Pharms. Inc. Sec. Litig*., No 01-1455, 2003 U.S. Dist LEXIS 7667, at *12-13 (S.D. Cal. May 1, 2003) (scienter adequately pleaded where there was a plausible inference that the

[44] *In re Astrazeneca Sec. Litig.,* No. 05 Civ. 2688, 2008 U.S. Dist. LEXIS 43680, at *43 (S.D.N.Y. June 3, 2008) (citing *Bayer*, 2004 U.S. Dist. LEXIS 19593).

[45] Comp. ¶¶ 60, 72, 95.

defendant "knew that there may be a problem with the methodology used…but took the calculated risk of continuing the trials and application process as originally planned…").

Moreover, the positions held by the Individual Defendants are also evidence of scienter as numerous courts have held that where the alleged fraud relates to the core business of the company, knowledge of the fraud can be imputed to its officers and directors. *See In re Atlas Air Worldwide Holdings, Inc. Sec. Litig*., 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004); *In re Cell Pathways Inc. Sec. Litig.*, No. 99-752, 2000 U.S. Dist. LEXIS 8584, at *22-23 (E.D. Pa. June 20, 2000) ("Where the alleged fraud relates to the core business of the company, knowledge of the fraud may be imputed to the individual defendants.") In *Atlas*, the Court reasoned that:

> [I]f facts that contradict a high-level officer's public statements were available when the statements were made, it is reasonable to conclude that the speaker had intimate knowledge of those facts or should have known of them. Accordingly, if a plaintiff can plead that a defendant made false or misleading statements when contradictory facts of critical importance to the company either were apparent, or should have been apparent, an inference arises that high-level officers and directors had knowledge of those facts by virtue of their positions with the company.[46]

The Complaint contains specific allegations that throughout the class period, the Individual Defendants had a clear understanding of the operations of the business and deliberately, or a least recklessly, misleadingly represented that the FDA had agreed to the use of PFS as a primary endpoint for the satraplatin trials. The Individual Defendants' knowledge of the Company's operations is demonstrated by the fact that they were all high level officers and members of GPC's Management Board (similar to a board of directors) during the Class Period and had direct involvement in the day-to-day management and operation of the Company.[47] Seizinger and Scherer (one of the Company's co-founders) signed Sarbanes-Oxley certifications

[46] 324 F. Supp. 2d at 489.

[47] Comp. ¶¶ 32-36, 38.

attached to the Company's Form 20-F annual report filings with the SEC, certifying that the information contained in the Company's annual reports fairly presented in all material respects the financial condition and results of GPC's core business operations. *Id.*

It is also important to note that, as alleged in the Complaint, the Individual Defendants were well aware that (1) the success of the Company depended on it obtaining the necessary governmental approvals to market and distribute satraplatin; and (2) that satraplatin was GPC's lead drug product candidate, upon which the Defendants concentrated substantially all of their efforts.[48] Given their focus on satraplatin as the Company's lead drug candidate, the Individual Defendants cannot feign ignorance about what the FDA said and more importantly, what the FDA did not say.

Defendants contend that the Company warned investors "about the possibility of the very outcome that led to their losses."[49] This argument has no merit. Defendants fail to explain what cautionary language warned investors about the specific losses that are the subject of this litigation (i.e. that Defendants publicly represented that that had an agreement with the FDA to use PFS as an acceptable endpoint, when in fact the Company never had such an agreement and misrepresented this material fact in some statements and omitted it from public disclosure in others). To the extent that the Defendants provided investors with any warnings, such warnings only related to the general risks that satraplatin might not be approved by the FDA and does not immunize defendants from liability. "[A]ll the cautionary language in the world will not replace

[48] Comp. ¶¶ 30, 95. *See also In re Vicuron Pharms., Inc. Secs. Litig.,* No. 04-2627, 2005 U.S. Dist. LEXIS 15613, at *28 (E.D. Pa. July 1, 2005) (the importance to the company of the lead drug under development warranted an inference of recklessness, at the least, of its officers and directors as to misstatements related to Phase 3 clinical trials of the drug); *In re Viropharma, Inc. Sec. Litig.,* No. 02-1627, 2003 U.S. Dist. LEXIS 5623, at *30-32 (E.D. Pa. Apr. 3, 2003) (scienter adequately pleaded since highest ranking officers of the company would have access to information concerning the company's leading product).

[49] Defendants' Brief at 25.

a true material omission or misstatement of a fact which would matter to a reasonable investor." *Integrated Res.,* 815 F. Supp. at 674.

2. Plaintiffs Allege Facts Demonstrating Motive and Opportunity

In addition to showing strong circumstantial evidence of conscious misbehavior or recklessness, the Complaint also satisfies the scienter pleading requirements by showing the clear existence of motive and opportunity. As set forth by the Second Circuit, "[m]otive" entails "concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged." "Opportunity" is having "the means and likely prospect of achieving concrete benefits by the means alleged." *Novak,* 216 F.3d at 307.

Defendants do not challenge Plaintiff's claim that Defendants had the opportunity to commit fraud. This is not surprising. The opportunity prong is rarely challenged because few doubt that senior executives can manipulate the price of their company's stock through fraud, if they so wish. *In re Time Warner Sec. Litig*., 9 F.3d 259, 269 (2d Cir. 1993) ("no one doubts that the defendants had the opportunity, if they wished, to manipulate the price of [the company's] stock"); *see also In re eSpeed, Inc. Sec. Litig*., 457 F. Supp. 2d 266, 281 (S.D.N.Y. 2006) ("courts often assume that corporations, corporate officers and corporate directors would have the opportunity to commit fraud if they so desired."); *In re Rhodia S.A. Sec. Litig.,* 531 F. Supp. 2d 527, 548 (S.D.N.Y. 2007) (citing *Kalnit*, 264 F.3d at 138 (finding that it may be presumed that corporate officers have the opportunity to commit fraudulent acts)).

Plaintiff's allegations also satisfy the test for showing that Defendants had a motive to commit fraud. For this reason, Defendants' challenges to Plaintiffs' scienter allegations fail, and their motion to dismiss should be denied.

The first of three satraplatin patents that GPC acquired was set to expire in 2008.[50] The only way the Company could extend the exclusivity period was to obtain some form of regulatory approval before its expiration.[51] Timing, therefore, dictated that Defendants pursue accelerated approval via the agency's fast track designation process, and so they did.[52]

In connection with their efforts to obtain fast-track designation and accelerated approval, Defendants met frequently with representatives of the FDA.[53] GPC received the FDA's permission to seek accelerated approval of satraplatin based on its showing that there were no comparable drugs already in the market, and upon showing that there was a need for treatment for prostate cancer patients who have relapsed once.[54]

With this as background, Plaintiff alleges that the Individual Defendants, seeking to ensure their own monetary gain, decided that they were going to profit from their efforts whether the application for satraplatin was approved, as they hoped, or not. To accomplish this, Defendants needed two things to happen: 1) the company had to raise the necessary funds to stay in business until the FDA ruled on its application; and 2) investors needed to believe that the satraplatin application would ultimately be approved.[55] This would allow Defendants to sell their shares at high, inflated prices.

Both elements were accomplished. Defendants issued a series of press releases, and reported at numerous conferences, that the clinical trials were going well and were showing that

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[50] Comp. ¶ 49.

[51] Defendants' argument that Hatch-Waxman would provide five years of data exclusivity is conditional on GPC's satraplatin application getting approved. "Further, as GPC explained, *if* satraplatin were approved, it would receive five years of data exclusivity as a "new chemical entity" under the Hatch-Waxman Act." Defendants' Brief at 26.

[52] Comp. ¶¶ 49-52.

[53] Comp. ¶ 52.

[54] Comp. ¶ 54.

[55] Comp. ¶¶ 6-7.

patients given satraplatin were living progression-free for longer than those given the placebo. These announcements, coupled with Defendants' statements that the FDA had approved PFS as the primary endpoint for the clinical trials, led to tremendous expectations in the financial community that the application would be approved.[56] This allowed the Company to sell additional shares to investors anticipating ultimate market approval, shares that they owned and shares issued by the Company.

Defendants were motivated not only to sell shares, but to sell at high prices. If Defendants disclosed that the FDA had informed them that the agency had no experience with the PFS endpoint (or with the composite elements of the PFS endpoints used by GPC in its clinical trial), the stock price would not have risen as it did. Having withheld this information, however, Defendants watched GPC's stock price rise throughout the class period, and from time to time, sold shares of GPC stock. All told, the Individual Defendants sold $39 million of their own personal holdings of GPC stock during the class period,[57] before the FDA ruled on GPC's application.

Plaintiff is not alone in seeing this motive. On August 2, 2007, an analyst with DZ Bank questioned the Individual Defendants' motivation, pointing out the patent-related need for accelerated approval, the need to raise funds, and the fact that Defendants sold shares before the FDA committee ruled. The analyst also made the point that by pursuing approval using a PFS-based endpoint – "albeit pursued here in disagreement with the FDA in detail- is often a less risky endpoint in oncology studies than meeting a survival advantage."[58]

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[56] Comp. ¶¶ 15, 82-84, 93.

[57] Comp. ¶ 16.

[58] Comp. ¶ 112.

By telling investors that the FDA had agreed to the use of PFS as an endpoint for the clinical trials, without telling them that the FDA said that it had no experience with that endpoint (or as Defendants claim, the manner in which GPC intended to demonstrate PFS), and by reporting positive clinical trial results, Defendants put themselves in a position to "cash out" before the FDA ruled. This is what motivated them not to disclose that the FDA had "clearly communicated to them" either that it was unfamiliar with the endpoint generally, or that it was unfamiliar with the manner in which GPC intended to demonstrate PFS.

The motive element can be supported when corporate insiders misrepresent material facts to keep the price of stock high while selling their own shares at a profit. *In re Scholastic Corp. Sec. Litig*., 252 F.3d 63, 75 (2d Cir. 2001) (citing *Novak*, 216 F.3d at 307-08). "Unusual" insider sales at times negative information is hidden may permit an inference of scienter. *Scholastic*, 252 F.3d at 75 (citing *Acito v. Imcera Group, Inc.*, 47 F.3d 47, 54 (2d Cir. 1995)). "Factors considered in determining whether insider trading activity is unusual include the amount of profit from the sales, the portion of stockholdings sold, the change in volume of insider sales, and the number of insiders selling." *Scholastic,* 252 F.3d at 75-76 *(*citing *Rothman,* 220 F.3d at 94).

Plaintiffs allege that during the Class Period, the Individual Defendants sold millions of shares of GPC securities for an aggregate in proceeds of more than 26 million euros.[59] The insider sales are highly unusual, particularly when viewed with close scrutiny. *In re Cardinal Health, Inc. Sec. Litig*., 426 F. Supp. 2d 688, 727 (S.D. Ohio 2006) ("insider trading at a suspicious time or in an unusual amount comprises one of the fixed constellations of facts that courts have found probative of securities fraud") (internal quotes omitted).

[59] Comp. ¶ 142.

Just a few weeks after the Company announced that it had achieved its target enrollment in the SPARC trial, the Individual Defendants sold collectively 394,785 shares of GPC stock for a total proceeds of 4.3 million euros.[60] Between March 2006 and November 2006, the Company reported numerous positive developments about the Company's fund raising and the SPARC trial that allowed The Individual Defendants the opportunity to sell an additional 1,016,445 shares of GPC stock for 17.4 million euros.[61] The insider sales were particularly suspect between May 21, 2007 and July 19, 2007 as these stock sales were made just weeks and days before the Company's meeting with the FDA committee, which allowed the Individual Defendants to cash in on more than 240,000 shares for total proceeds of 5.2 million euros.[62] Undoubtedly, the Individual Defendants' coordinated insider sales were made at suspicious times and in unusual amount and therefore support a strong inference of scienter.

The Individual Defendants contend that their insider sales were irrelevant because under Rule 10b5-1, if stock sales are made pursuant to a valid trading plan, a seller may assert an affirmative defense to claims of insider selling.[63] However, in order for a pre-arranged stock trading plan to support an affirmative defense, a defendant needs to establish that the plan was entered into in good faith and before the insider became aware of material nonpublic information. *See In re Audible Inc. Sec. Litig*., No. 05-1027, 2007 U.S. Dist. LEXIS 25068, at *11 n.7 (D.N.J. Apr. 3, 2007) ("A 10(b)5-1 plan provides an affirmative defense to an allegation of insider trading. However, the plan must have been adopted prior to the person becoming aware of the material, non-public information. 17 C.F.R. § 240.10b5-1(c)).”

[60] Comp. ¶¶ 62, 65.
[61] Comp. ¶¶ 70, 72, 73, 75, 77, 78, 79.
[62] Comp. ¶¶ 97-99.
[63] Defendants' Brief at 28.

As alleged in the Complaint, all of the stock that was sold pursuant to the Individual Defendants' trading plans was sold pursuant to plans created after the Individual Defendants learned from the FDA that the primary endpoint they selected for the SPARC trial, PFS (or as Defendants contend, the component parts of PFS used by GPC), was an endpoint (or were component parts of the proposed endpoint) with which the FDA had no experience.[64] As such, Defendants cannot show that they entered into these plans in good faith, before they knew that the FDA had any issues with PFS endpoint.

Moreover, any serious evaluation of the Individual Defendants' purported trading plans would need a fully developed record and is premature to evaluate at the motion to dismiss stage. *See, e.g., In re Fannie Mae Sec., Derivative, & "ERISA" Litig.,* 503 F. Supp. 2d 25, 48 (D.D.C. 2007) (Court concluded that defendants' motion to dismiss claims of insider trading were premature); *Cardinal Health,* 426 F. Supp. 2d at 734 (declining to consider 10b5-1 trading plan as an affirmative defense to insider trading allegations because it is "typically premature to raise affirmative defenses in a motion to dismiss."); *In re Cray Inc. Derivative Litig*., 431 F. Supp. 2d 1114, 1131 (W.D. Wash. 2006) (declining to dismiss insider trading claim based on 10b5-1 trading plan because plan is affirmative defense on which defendants bear burden of proof).

Plaintiffs' allegations of motive serve to supplement their recklessness allegations, the latter which, by themselves, satisfy the scienter requirement. Nonetheless, taken as a whole, the Complaint adequately pleads an inference of scienter as to each of the Individual Defendants that is cogent and at least as compelling as any plausible opposing inference of non-fraudulent intent.

[64] Comp. ¶¶ 66, 80, 100.

III. The Complaint States A Claim for Violations of Section 20A

Plaintiffs have adequately pled Section 20A claims for illegal insider trading against the Individual Defendants.[65] Section 20A(a) of the Exchange Act creates a private right of action to address insider trading, providing that:

> Any person who violates any provision of [the Exchange Act] or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . securities of the same class.

15 U.S.C. § 78t-1(a). A plaintiff states a claim under Section 20A(a) by pleading: "(1) a predicate insider trading violation of the Exchange Act, (2) 'that the defendant traded the security at issue 'contemporaneously' with the plaintiff,' and; (3) that the defendant was 'in possession of material, nonpublic information' at the time of the trade." *In re Openwave Sys. Sec. Litig.*, 528 F. Supp. 2d 236, 255 (S.D.N.Y 2007) (internal citations omitted).

In the Second Circuit, "trades are contemporaneous if they occur within a reasonable period of time…of one another." *In re Take-Two Interactive Sec. Litig.*, No. 06-803, 2008 U.S. Dist. LEXIS 31463, at *181 n.51 (S.D.N.Y. Apr. 16, 2008); *see also Openwave,* 528 F. Supp. 2d at 256 n. 12 (finding that contemporaneousness was adequately alleged where plaintiffs specifically alleged dates on which insider sales occurred and further found that class members had purchased shares contemporaneously with those sales); *In Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133, 144 (S.D.N.Y. 1999) (holding that "standard for contemporaneity is a reasonable period" and ruling that trades falling within five days of alleged insider trades were contemporaneous); *In re Am. Bus. Computers Corp. Sec. Litig.*, No. MDL-913, 1994 U.S. Dist. LEXIS 21467, at *10 (S.D.N.Y. Feb. 24, 1994) ("the term 'contemporaneously' may embrace

[65] Comp. ¶¶ 139-146.

the entire period while relevant material non-public information remained undisclosed")); *In re Countrywide Fin. Corp. Derivative Litig.*, No. 07-6923, 2008 U.S. Dist. LEXIS 40754, at *81 (C.D. Cal. May 14, 2008) ("The duration of the period in which an insider defendant's trade can be considered 'contemporaneous' with the plaintiff's is 'not fixed'…").

As detailed in the Complaint, the profits from the Individual Defendants' sales were in aggregate more than 26 million euros.[66] Here, plaintiffs allege that the Individual Defendants sold GPC securities when they knew (and the public did not) that the FDA was not familiar with "progression-free survival" as a primary endpoint for the Company's SPARC study (of its component parts as proposed by Defendants). Nevertheless, the Individual Defendants claim that the Plaintiff's section 20A claim fails for lack of an allegation that its trades occurred contemporaneously.[67] As set forth below, however, Lead Plaintiff purchased GPC securities on June 11 and July 23, 2007, and Plaintiff Chua purchased GPC securities on June 12, 2007,[68] which were made "contemporaneously" with the sales of GPC securities by the Individual Defendants on June 12, 2007 (Maier), June 15, 2007 (Maier), June 18, 2007 (Ewert), June 19, 2007 (Ewert), July 13, 2007 (Scherer) and July 19, 2007 (Seizinger).[69]

[66] Comp. ¶¶ 16, 142

[67] Defendants' Brief at 32-33.

[68] Defendants concede that Plaintiff Chua's purchases on June 12, 2007 were made contemporaneously with the insider sales of defendant Maier. *See* Defendants' Brief at 33.

[69] Comp. ¶¶ 99, 144

Name	Date of Transaction	Number of Shares	Avg. Share Price (Euros)	Total Proceeds (Euros)
Maier	6/12/2007	1,254	20.09	25,197
	6/15/2007	9,996	20.05	200,468
	6/15/2007	11,250	20.06	225,675
Ewert	6/18/2007	5,000	20.22	101,100
	6/19/2007	5,000	19.91	99,550
Scherer	7/13/2007	26,916	22.50	605,610
	7/13/2007	12,500	22.80	285,000
Seizinger	7/19/2007	75,660	22.94	1,735,640

IV. The Complaint Adequately Alleges Control Person Liability

A plaintiff pleads a *prima facie* case of control person liability under Section 20(a) by alleging "(1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI Commc'ns*, 493 F.3d at 108 (citing *SEC v. First Jersey Sec., Inc*., 101 F.3d 1450, 1472 (2d Cir. 1996)). "Allegations of control are not averments of fraud and therefore need not be pleaded with particularity." *In re Parmalat Sec. Litig*., 414 F. Supp. 2d 428, 440 (S.D.N.Y. 2006). All that is required is "[a] short, plain statement that gives the defendant fair notice of the claim that the defendant was a control person and the ground on which it rests its assertion that a defendant was a control person." *In re WorldCom, Inc. Sec. Litig.*, 294 F. Supp. 2d 392, 415-16 (S.D.N.Y. 2003). It is perfectly proper to plead a claim under Section 20(a) against a defendant not alleged to have violated Section 10(b). *See, e.g., In*

re Tommy Hilfiger Sec. Litig., No. 04-7678, 2007 U.S. Dist. LEXIS 55088, at *13 (S.D.N.Y. July 20, 2007).

The only element of "control person" liability challenged by Defendants is the first one. Defendants claim that because there was no primary violation, there can be no control person liability.[70] For the reasons set forth in Section II, *supra,* Plaintiff has stated a claim for violation of Section 10(b) against GPC. All of the other elements of a Section 20(a) claim are pled in the Complaint. Accordingly, Defendants' motion to dismiss Plaintiff's 20(a) claim against the four Individual Defendants should be denied.

V. If Needed, Plaintiff Should Be Granted Leave to Amend

Plaintiffs should be granted leave to amend in the event that the Court grants Defendants' motion in any respect. Fed. R. Civ. P. 15(a) provides that "leave [to amend] shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Whether to grant a plaintiff leave to amend is within the sound discretion of the court. *Scottish Re Group*, 524 F. Supp. 2d at 388. "Moreover, '[i]t is the usual practice upon granting a motion to dismiss to allow leave to replead'", particularly when deciding a motion to dismiss brought under Rule 12(b)(6) and Rule 9(b). *Id.* at 387-88 (quoting *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F. 2d 42, 48 (2d Cir. 1991)).

[70] Defendants' Brief at 30-31.

CONCLUSION

For the foregoing reasons, Plaintiff requests that Defendants' Motion to Dismiss the Consolidated Class Action Complaint be denied in its entirety.

Dated: June 30, 2008

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